UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNIVERSITY OF ROCHESTER, a New York Education Corporation,

Plaintiff,

DECISION AND ORDER

00-CV-6161L

v.

G.D. SEARLE & CO., INC., a Delaware Corporation, et al.,

Defendants.

Patent law often involves subject matter and legal principles that can be both complex and arcane. But there are some basic principles that should be evident even to the lay person.

An "inventor" or patentee is entitled to a patent to protect his work but only if he produces or has possession of something truly new and novel. The "invention" he claims must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection.

The patent at issue here does not do that. What the reader learns from this patent is a wish or plan or first step for obtaining a desired result. What he appreciates is that the patentee had a goal for achieving a certain end result. The reader can certainly appreciate the goal but establishing goals

does not a patent make. The reader also learns that the patentee had not proceeded to do what was necessary to accomplish the desired end. In my view, such an "invention" is not really one at all. As the Court of Appeals for the Federal Circuit stated in a case involving similar issues, an inadequate patent description that merely identifies a plan to accomplish an intended result "is an attempt to preempt the future before it has arrived." *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir. 1993). Such a patent fails to comply with the requirements of the federal statutes concerning issuance of patents and, therefore, must be held invalid.

BACKGROUND

The patent at issue, United States Patent No. 6,048,850 ("the '850 patent") relates to a new generation of pain relief medication that does not produce certain undesirable side effects, particularly stomach irritation, associated with many other pain relievers such as aspirin, acetominophen, ibuprofen, etc. Specifically, the '850 patent claims a pharmaceutical "method for selectively inhibiting PGHS-2 activity in a human host" in which "the activity of PGHS-1 is not inhibited." '850 Patent, col. 71, lines 36-37, 43-44. PGHS-1 and PGHS-2[1] are two enzymes produced by the human body. They play a role in the manufacture of hormones known as prostaglandins.

Prostaglandins perform various functions; prostaglandins produced through the activity of PGHS-1, for example, are beneficial and help protect the stomach lining. PGHS-2, on the other

[1]PGHS-1 and PGHS-2 are also sometimes referred to as Cox-1 and Cox-2. These terms are taken from the chemical names prostaglandin H synthase and cyclooxygenase.

hand, is associated with inflammatory stimuli. When those stimuli are present, production of PGHS-2 increases, which in turn leads to an increase in the prostaglandins produced through the activity of PGHS-2. Those prostaglandins, however, cause pain and inflammation.

For many years, it was not known that in mammals, there are these two cyclooxygenase enzymes, *i.e.*, PGHS-1 and PGHS-2. Many pain relievers that were employed prior to the discovery that there were two such enzymes used non-steroidal anti-inflammatory drugs ("NSAIDs"), which inhibited the activity of both PGHS-1 and PGHS-2. This resulted in relief from the pain and inflammation associated with PGHS-2, but also caused stomach upset and irritation because of the lowered levels of PGHS-1.

The claimed invention here arises out of the discovery in the early 1990s by scientists at the University of Rochester of the existence of PGHS-2, and its separate functions from those performed by PGHS-1. The inventors theorized that if a method were found of targeting PGHS-2 alone, without affecting PGHS-1 activity, it would be possible to provide relief from pain and inflammation without the gastrointestinal side effects associated with most NSAIDs. In other words, the goal was to reduce PGHS-2 activity, which causes pain and inflamation, without adversely affecting PGHS-1 activity, which is beneficial because, in part, it acts to reduce stomach irritation.

To that end, the scientists developed an assay for determining whether a particular non-steroidal compound is suitable for use in practicing the claimed invention. That assay, which is described in § 5.6 and in claim 6 of the patent, involves contacting genetically engineered cells containing either PGHS-1 or PGHS-2, but not both, with the compound being tested, exposing the cell and compound to a predetermined amount of arachidonic acid (which is capable of being transformed into a prostaglandin) for thirty minutes, and then determining the extent to which the

acid in each cell has been converted into prostaglandin, compared to the amount transformed in control cells that were not exposed to the compound. As stated by plaintiff's counsel at oral argument, this assay essentially involves "run[ning a compound] through the assay to figure out which compound hybridizes to cyclooxygenase-2 and prevents its activity, but don't [sic] affect the activity of cyclooxygenase-1." Transcript, July 25, 2002 (Docket #247) at 18, lines 13-16. In other words, the compound is simply tested to see whether or not it performs in the manner called for by the method described in the '850 patent.

On April 11, 2000 -- the same day that the '850 patent was issued -- the University of Rochester brought this patent infringement action against defendants G.D. Searle & Co., Inc. ("Searle"), Pfizer, Inc., Monsanto Co., and Pharmacia Corp., seeking injunctive relief and damages for alleged infringement of the '850 patent. Defendants have moved for summary judgment of patent invalidity on the ground that the '850 patent does not comply with the written-description requirement of 35 U.S.C. § 112, ¶ 1. Defendants base this assertion on the fact that while the patent calls for use of a "compound" that selectively inhibits PGHS-2 activity, the patent specification does not identify any such compound. Plaintiff has cross-moved for summary judgment on the same issue, seeking an order finding that the '850 patent is not invalid for failure to meet the written-description requirement.

Defendants have also moved for summary judgment of patent invalidity for non-enablement, arguing that the '850 patent fails to describe the invention in terms sufficient "to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" the invention. 35 U.S.C. § 112.

DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable factfinder could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 980 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Anderson*, 477 U.S. at 248; *General Mills*, 103 F.3d at 980.

"When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001) (citing *Anderson*, 477 U.S. at 252-53), *cert. denied*, 534 U.S. 1109 (2002). In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor. *Anderson*; 477 U.S. at 255; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274 (Fed.Cir.1995).

Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through clear and convincing evidence, *see Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998); *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1563 (Fed. Cir.), *cert. denied*, 522 U.S. 950 (1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held

not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable finder of fact could invalidate the patent. *Eli Lilly*, 251 F.3d at 962.

II. Written-Description Requirement

A. General Standards

Defendants assert that the '850 patent is invalid for failure to comply with the written-description requirement. That requirement is contained in 35 U.S.C. § 112, ¶ 1, which provides that

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ... .

Whether a specification complies with the written-description requirement is a question of fact. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985). As in other areas of the law, however, if the court finds that there is no genuine issue of material fact as to this issue, summary judgment is appropriate. *See*, *e.g.*, *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1120 (Fed. Cir. 2001) (affirming summary judgment of invalidity for failure to meet written-description requirement).

In the case at bar, both sides have moved for summary judgment on the written-description issue and, therefore, neither believes that there are fact issues. While that fact does not necessarily mean that either of them is entitled to summary judgment, *see, e.g.*, *BBS Power Mod, Inc. v. Prestolite Elec., Inc.*, 71 F.Supp.2d 194, 202 (W.D.N.Y. 1999) (denying cross-motions for summary

judgment on ground that genuine issues of material fact existed), it does suggest that there are no issues of fact here, and I find that there are none.

Although compliance with § 112, ¶ 1 is a factual issue that must be determined on a case-by-case basis, the real issue here is simply whether a written description of a claimed method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial-and-error process.[2]

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; *see also Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the

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[2]Plaintiff also contends that the Court must first construe the claims of the '850 patent before deciding the written-description issue. Although the Federal Circuit has stated that "[t]he first step in any invalidity analysis is claim construction ...," *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000), a court need not decide the meaning of all disputed claims if the construction of the claims would have no bearing on the invalidity analysis. *See*, *e.g.*, *id.* (finding it unnecessary to decide whether district court correctly construed the term "cell," since claim in question was obvious in any event). In the instant case, plaintiff has advanced no construction of any of the claims of the '850 patent that would bear upon the written-description issue, or that would affect my decision on that issue. In particular, regardless of whether the Court adopts plaintiff's proffered construction of the claims, the '850 patent still requires the use of a "compound" that is defined in terms of its ability to selectively inhibit the activity of PGHS-2 and not that of PGHS-1.

written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

B. Biotechnology Patents–Defining a Substance by its Function

The Court of Appeals for the Federal Circuit has on more than one occasion discussed the written-description requirement as it applies to biotechnology patents, particularly those in which a substance is defined only by a description of its function or the desired result of its use. For example, in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998), the court affirmed a district court ruling that all of the claims of a patent were invalid because the specification did not provide an adequate written description of the rat DNA that was required by the asserted claims. The court said that "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1171).

Likewise, in *Fiers*, the court held (in the context of an interference proceeding) that a patent application failed to satisfy the written-description requirement where the claimed invention called for a "DNA which codes for a human fibroblast interferon-beta polypeptide" ("β-IF"), and the application disclosed a method for isolating a fragment of the DNA coding for β-IF as well as a method for isolating messenger RNA coding for β-IF, but did not disclose a complete DNA sequence coding for β-IF. In reaching that holding, the court stated that "[a]n adequate written

description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." 984 F.2d at 1170. The court stated that the disclosure contained in the application "just represents a wish, or arguably a plan, for obtaining the DNA," and that "it does not indicate that [the applicant] was in possession of the DNA." *Id.* at 1171. The court added that a description of DNA requires "a precise definition, such as by structure, formula, chemical name, or physical properties ... ." As referenced above, the court said that "[c]laiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." *Id.*

The Federal Circuit recently revisited this area in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002). The patent in that action was directed to a "nucleic acid probe" that would selectively hybridize, or bind, to the genetic material of the bacteria that cause gonorrhea. The patentee derived three biochemical sequences that were able to achieve the desired result, which the patentee deposited in the form of a DNA molecule within an E. coli bacterial host at the American Type Culture Collection.

The patentee sued two of its competitors for infringement, and the defendants moved for summary judgment on the ground that the claims were invalid for failure to meet the written-description requirement. The district court granted the motion, concluding that the claimed composition of matter was defined only by its biological activity or function, which it held was insufficient to satisfy § 112, ¶ 1.

The Federal Circuit initially affirmed, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002), but on rehearing, the court determined that its initial ruling that a deposit may not

satisfy the written-description requirement was incorrect. The court therefore vacated its prior decision and reversed summary judgment, finding that genuine issues of material fact existed regarding satisfaction of the written-description requirement. 296 F.3d 1316.

In so holding, however, the court did not overturn its prior case law that "a mere wish or plan" for obtaining an invention is not enough to comply with § 112, ¶ 1. *Id.* at 1324 (quoting *Eli Lilly*, 119 F.3d at 1566). While the court did state that "[i]t is not correct ... that all functional descriptions of genetic material fail to meet the written description requirement," *id.*, the court did *not* hold that all such functional descriptions *are* sufficient. Rather, the court adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics *when coupled with a known or disclosed correlation between function and structure ...* ." *Enzo*, 296 F.3d at 1324-25 (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Applying that standard, the court held that "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Id.* at 1325.

As to the patent before it, the court, noting that the claims were not limited to the deposited sequences, but were also directed to subsequences of the deposited sequences and mutated variations thereof, the number of which might have been "astronomical," *id.* at 1326, held that there was an

issue of fact as to whether the reference in the patent to the deposited sequences would describe those subsequences and variations to one of skill in the art sufficiently to demonstrate possession of the generic scope of the claims. *Id.* at 1327.[3]

Notably, however, the court rejected the plaintiff's argument that the written-description requirement for the generic claims was necessarily met as a matter of law because the claim language appeared *in ipsis verbis* in the specification. Stating that "[e]ven if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed," *id.* at 1328, the court stated, as an example, that a

> description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. Similarly, the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity. *A description of what a material does, rather than of what it is, usually does not suffice*.

Id. at 1329 (citing *Eli Lilly*, 119 F.3d at 1568) (emphasis added).

C. Written-Description Requirement as Applied to the '850 Patent

Applying these principles to the case at bar, I conclude that, as a matter of law, the '850 patent does not comply with the written-description requirement of § 112, and that defendants are

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[3]The court also held that the patentee had raised a genuine issue of material fact as to whether a reasonable factfinder could conclude that the claimed sequences were described by their ability to hybridize to certain strains of gonorrhea bacteria whose genomic DNA, while not explicitly sequenced in the patent, was accessible to the public, since those bacteria had also been deposited. The court held that "[s]uch hybridization to disclosed organisms may meet the PTO's Guidelines stating that functional claiming is permissible when the claimed material hybridizes to a disclosed substrate." *Id.* at 1328.

therefore entitled to summary judgment on that issue. The patent does no more than describe the desired function of the compound called for, and it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work.

The specification states that the invention comprises, *inter alia*, "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product; and methods of treating diseases characterized by aberrant PGHS-2 activity using such compounds." '850 Patent, col. 8, lines 2-7. Nowhere, however, does it specify *which* "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.[4]

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[4]The patent does state that one compound, NS-398, is a "specific inhibitor of PGHS-2," '850 Patent col. 28 line 40. The inventors testified that they do not know if NS-398 can in fact be used in the claimed treatment method, however. *See* Deposition of Donald A. Young (Docket #172, Ex. B), at 140; Deposition of Michael K. O'Banion (Docket #172, Ex. C), at 183-88. In response to defendants' request to admit that NS-398 is "a steroidal compound that selectively inhibits activity of the PGHS-2 gene product" as that expression is used in claim 1 of the '850 patent, plaintiff responded, in part, that it "cannot admit or deny the truthfulness of the statement ... without surveying an entire body of scientific work concerning the chemical 'NS-398'" and arranging for expert review of that body of work. Docket #172, Ex. D, at 16.

Defendants also allege that NS-398 was publicly described as an anti-inflammatory agent for use in humans more than a year before the earliest application for the '850 patent was filed. *See* European Patent Application No. 88310899.5 (pub. May 24, 1989) (Docket #172, Ex. E). Defendants contend that if the '850 patent method claims covered the administration of NS-398 to a human, the claims would be invalid as anticipated under 35 U.S.C. § 102(b). *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001) ("it is axiomatic that that which would literally infringe if later anticipates if earlier"); *EMI Group North America Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349 (Fed. Cir. 2001) ("the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to

(continued...)

Likewise, § 5.6 of the patent describes in detail the screening assay, "which will be useful for the development of drugs that selectively inhibit inflammation without producing the side effects due to inhibition of constitutive [*i.e.*, PGHS-1] prostaglandin production," but it does not identify any particular drugs that the assay will identify as suitable for this purpose. '850 Patent, col. 24, lines 34-37.

Section 5.7, captioned "compounds identified in the screens," which might be expected to state which compounds had been identified by the inventors, instead states simply that "[t]he compounds identified in the screen will demonstrate the ability to selectively modulate the expression of PGHS-2. These compounds include but are not limited to nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof, as well as antisense, ribozyme, triple helix, antibody, and polypeptide molecules and small inorganic molecules." '850 Patent, col. 27, lines 29-35. There is no indication that the inventors themselves had identified any such compounds from among those listed, however.

The claims themselves add no further specificity, stating only that the patent claims, *inter alia*, a method "comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment ... in which the compound

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[4](...continued)
the discoverer") (quoting *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999)).

Although plaintiff states that it disputes defendants' assertion that NS-398 was so published in the prior art, Plaintiff's Statement of Undisputed Facts (Docket #208) ¶ 10, it does so on the ground that plaintiff "does not understand" this assertion, and it offers no evidence to the contrary. *Id.* At any rate, plaintiff does not appear to argue that the patent's reference to NS-398 suffices to meet the requirements of § 112, ¶ 1.

inhibits the enzymatic activity of the PGHS-2 gene product, and has minimal effect on enzymatic activity of PGHS-1." '850 Patent, col. 71, lines 36-42.

In none of these descriptions, then, is there even any suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention. Instead, these purported descriptions of the needed compound are, insofar as their sufficiency for purposes of the written-description requirement is concerned, virtually indistinguishable from the *Enzo* court's example of a description of an anti-inflammatory steroid couched "in terms of its function of lessening inflammation of tissues," which, the court stated, "fails to distinguish any steroid from others having the same activity or function," and which therefore fails to satisfy the written-description requirement.

I am not persuaded by plaintiff's contention that the holdings of *Enzo*, *Lilly*, and *Fiers* are limited to claims directed to DNA or nucleic acid sequences. That assertion is simply not supported by the language of the cases themselves. In *Fiers*, for instance, the Court of Appeals stated that "conception of a DNA, like conception of *any chemical substance*, requires a definition of that substance other than by its functional utility," 984 F.2d at 1169. Although the court there was discussing conception rather than written description, the court also stated that "[i]f a *conception* of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a *description* also requires that degree of specificity," since "one cannot describe what one has not conceived." *Id.* at 1171 (emphasis added).

In *Eli Lilly*, the court did draw a distinction between genetic material and other chemicals, stating that generic descriptions, which may be sufficient in claims involving other types of chemical materials, will often not suffice in claims to genetic material. The court said that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

119 F.3d at 1568.

In drawing this distinction, however, the court also stated that "[i]n claims involving [non-genetic] chemical materials, generic formulae *usually indicate with specificity what the generic claims encompass*. One skilled in the art can distinguish such a formula from others and *can identify many of the species* that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." *Id.* (emphasis added). There is no such specificity here, nor could one skilled in the art identify any particular compound encompassed by the claims. To the contrary, the specification states that suitable compounds *might* be found from among an array of organic and inorganic materials.

The *Lilly* court also stated that "[t]he description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention." *Id.* This statement was not qualified by reference to genetic material, and the case cited by the court in support of that statement, *In re Wilder*, 736 F.2d 1516 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985), did not involve any chemical-related claims, but claims directed to a mechanism for indicating the location of information recorded on a dictating machine. The *Wilder* court affirmed the PTO's rejection of those claims because the specification did "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate." *Id.* at 1521.

The *Enzo* court likewise did not indicate that its holding was limited to claims involving DNA. It is noteworthy that neither of the examples given by the court of insufficient descriptions were descriptions of genetic material, but of "an anti-inflammatory steroid" and "an antibiotic penicillin."[5]

Furthermore, to the extent that the *Enzo* court held that a functional description can meet the written-description requirement, it did so in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when *coupled* with a known or disclosed correlation between function and structure ... ." No such correlation has been disclosed here.

Consistent with that standard, the central holding of *Enzo* was that with respect to "biological materials," *id.* at 1325, (a term which presumably encompasses more than simply genetic material), "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Id.* In other words, it is not be necessary to give a precise chemical formula or description of a chemical structure when persons of ordinary skill in the art can ascertain what substance is being described by resort to the public depository where a specimen of that substance is kept. In the case at bar, however, no such deposit has been made.

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[5]I also note that the '850 patent itself purports to encompass nucleic acid; it states that among the compounds that might be identified through the claimed assay are "nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof ... ." '850 Patent, col. 27, lines 31-35.

Plaintiff has cited several cases decided by the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals, for the proposition that various types of descriptions, which do not necessarily include precise chemical formulas, can suffice to meet the written-description requirement with respect to chemical compounds. In finding that the '850 patent is deficient in that regard, however, I do not hold that it is a *sine qua non* that the patent set forth the exact chemical structure of the compounds in question. It is only necessary that the patent set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed. This the '850 patent fails to do.

The cases cited by plaintiff are not to the contrary. *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1183 (2001), for example, involved a patent claiming automotive gasoline compositions that reduced tailpipe emissions. Although "the claims d[id] not describe each gasoline product in terms of molecular structures or lists of ingredients," but rather "specif[ied] the chemical properties of the gasolines," this description "reflect[ed] the way oil refiners formulate gasoline," so that "the claims which define[d] the invention in terms of various characteristics also inform[ed] those of skill in the art of the composition of the claimed gasoline fuels." *Id.* at 992.

Union Oil and the other cases relied upon by plaintiff, such as *In re Herscher*, 591 F.2d 693 (C.C.P.A. 1979), and *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1978), indicate, as this Court has recognized, that it is not always necessary to set forth exact chemical formulas to satisfy § 112, ¶ 1, but they do not hold that a functional description of a chemical compound is necessarily sufficient. Rather, these cases simply reflect the fact that "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature

of the invention claimed.'" *Enzo*, 296 F.3d at 1324 (quoting *Vas-Cath*, 935 F.2d at 1563). In all of those cases, however, the description was found to contain enough information to lead a person skilled in the art to the claimed compound. *See Herschler*, 591 F.2d at 701 (finding that "the array of information supplied by appellant in the great-grandparent application [would] teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process"); *Edwards*, 568 F.2d at 1352, 1354 (application which described claimed compound by the process of making it contained adequate description, since "[i]t [wa]s undisputed that the ... reactions [set forth in the application] will inherently produce, as the predominant component, the claimed compound"; the "application, taken as a whole, reasonably leads persons skilled in the art ... to the claimed compound"). The '850 patent is completely lacking in that respect.

Plaintiff also argues that the requirements for written descriptions of claims to chemical compounds are irrelevant to this case because the '850 patent does not claim a compound, but a method of treatment by targeting PGHS-2 activity over PGHS-1 activity. Virtually any compound claim could be transformed into a method claim, however, simply by means of wording the claim in terms of a method of using the compound. With respect to the issue before the Court, then, this is little more than a semantic distinction without a difference. The claimed method *depends* upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, as defendants argue, akin to "inventing" a cure for cancer by utilizing a substance that attacks and destroys cancer cells while

leaving healthy cells alone. Without possession of such a substance, such a "cure" is illusory, and there is no meaningful possession of the method.

I recognize that the inventors and the research teams of which they were a part did apparently make some significant discoveries in this field. They realized, in light of the discovery of PGHS-2, that it would be quite beneficial if one could find a compound that would specifically target the activity of PGHS-2, but not that of PGHS-1.

What the inventors did *not* do, however, is succeed in taking the last, critical step of actually isolating such a compound, or at least of developing a process through which one skilled in the art would be directly led to such a compound. Absent that step, their discoveries, valuable though they might have been, did not blossom into a full-fledged, complete invention. Scientific discoveries, and theories based on those discoveries, frequently lay the groundwork for later inventions, but that does not make the discoverer the inventor as well.

In reaching this conclusion, the Court has also reviewed the declarations of plaintiff's two experts, Drs. Edward Dennis, who holds a Ph.D. in Chemistry, and John McGiff, M.D., a pharmacology professor at New York Medical College in Valhalla, New York. They both opine that the first application in the series of applications leading to issuance of the '850 patent ("the '780 application") "reasonably conveys to the ordinary skilled team of workers that the University [of Rochester] inventors were in possession of the inventions claimed in the '850 patent as of September 22, 1992," *i.e.* the date the application was filed. McGiff. Decl. ¶ 10; Dennis Decl. ¶ 32.[6]

[6]Dennis and McGiff agree that "one" of ordinary skill in the art to which the '850 patent pertains is a team of scientists, with skills in medicinal chemistry, molecular biology, biochemistry, and pharmacology. Dennis Decl. ¶ 15; McGiff Decl. ¶ 7.

Dennis and McGiff agree that "[t]he '850 patent does not contain claims to any compounds, but rather claims their use in this novel method of treatment." Dennis Decl. ¶ 12; McGiff Decl. ¶ 5. They state that "it would not be necessary for one of ordinary skill in the art to know the structure of a compound before screening it to determine whether it was suitable for use in the claimed method." According to them, "one of ordinary skill in the art would expect that compounds suitable for use in the claimed methods could be identified using known non-steroid anti-inflammatory compounds as a starting point in the screening process." Dennis Decl. ¶ 13; McGiff Decl. ¶ 6.

What this amounts to, though, is once again simply trial and error. Knowing the "starting point" is not enough; that is little more than a research plan. The patent describes how to test compounds to determine whether they work, but it does not set forth any procedure that will necessarily lead to discovery of such a compound, nor does it even identify any particular class of compounds that contains at least one suitable member. *Cf. Herschler*, 591 F.2d at 701 (finding that "the array of information supplied by appellant ... [would] teach one having ordinary skill in this art that one of the class of steroids *will operate* in the claimed process") (emphasis added); *Edwards*, 568 F.2d at 1354 (description of process for making claimed compound was adequate, since described process "will inherently produce ... the claimed compound").[7]

Tellingly, then, what plaintiff's experts' do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds–which, as the patent makes clear, are

[7]I recognize that *Edwards* involved a claim to a compound, whereas the '850 patent claims a method. The point is that the process described in the '850 patent will not "inherently produce" or lead to performance of the claimed method, since the method cannot be performed without a suitable compound.

necessary to practice the claimed method–would be suitable, nor would one know how to find such a compound except through trial and error, which hardly suggests conception of a complete invention. Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of that method–a compound that selectively inhibits PGHS-2 activity–was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

At one level, certainly, the claimed method is easy enough to understand. One simply administers a "compound" that inhibits the activity of PGHS-2 but not that of PGHS-1. Section 112, ¶ 1, however, requires the patentee to "show that an invention is *complete* by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was *in possession* of the claimed invention ... ." Guidelines, 66 F.R. at 1106 (emphasis added); *see also New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002) ("the disclosure must show [that the inventor] had invented *each feature* that is included as a claim limitation") (emphasis added). Even if the inventors were reasonably certain that the necessary compound existed and could eventually be found, there is no showing in the patent that they knew that to be a fact. In short, without possession, or at least knowledge, of such a compound, or of a method certain to yield such a compound, the inventors could not have possessed the claimed invention, *i.e.*, a method of treatment using the compound. *See Vas-Cath*, 935 F.3d 1563-64 ("the applicant must ... convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention"); *see also New Railhead Mfg.*, 298 F.3d at

1295 ("the [written description] requirement is not satisfied if one of ordinary skill in the art must first make the patented invention before he can ascertain the claimed features of that invention").

In effect, then, the '850 patent claims a method that cannot be practiced until one discovers a compound that was not in the possession of, or known to, the inventors themselves. Putting the claimed method into practice awaited someone actually discovering a necessary component of the invention. In some ways, this is reminiscent of the search for the so-called "philosopher's stone," eagerly sought after by medieval alchemists, which supposedly would transmute lead into gold. While the Court does not mean to suggest that the inventors' significant work in this field is on a par with alchemy, the fact remains that without the compound called for in the patent, the inventors could no more be said to have possessed the *complete* invention claimed by the '850 patent than the alchemists possessed a method of turning base metals into gold.[8]

The Federal Circuit in *Fiers* made the following observation about "[t]he difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function":

> would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans. While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity.

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[8]A patent for the philosopher's stone was actually issued during the reign of Edward III. "The invention we now regard as a superstition, but the application was referred by the King to a commission, which reported favorably upon it, and the patent issued apparently upon what we now regard as sound doctrine, that the invention was new and useful." *McKeever v. United States*, 14 Ct.Cl. 396 (1878). It is not apparent whether the patentee claimed actually to possess the stone, or whether he simply described it in terms of its function, in the hope that he would be entitled to royalties should it ever be discovered.

Fiers, 984 F.2d at 1169. That concern is well illustrated by the case at bar.

III. Enablement Requirement

A. General Standards

Section 112 provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ... ." This requirement "demands that the patent specification enable 'those skilled in the art to make and use the full scope of the claimed invention without undue experimentation.'" *National Recovery Technologies, Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir.), *cert. denied*, 522 U.S. 963 (1997)) (internal quote omitted).

Whether a patent complies with the enablement requirement is a question of law, *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690 (Fed. Cir. 2001); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987), although "the ultimate legal conclusion of enablement rests on factual underpinnings." *Union Pacific Resources*, 236 F.3d at 690. Enablement is determined as of the effective filing date of the patent, *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003) (citing *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977)). As with the written-description requirement, the burden of showing invalidity due to nonenablement is on the party asserting the defense. *See*, *e.g.*, *Morton, Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

Particularly disputed here is whether the '850 patent requires "undue experimentation" before the claimed invention can be practiced by those skilled in the art. "To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech*, 108 F.3d at 1365 (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that

> [t]he test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed.Cir. 1996) (quotation and citation omitted); *see also In re Wands*, 858 F.2d 731, 736-40 (Fed. Cir. 1988) ("The key word is 'undue,' not 'experimentation'") (quoting *In re Angstadt*, 537 F.2d 498, 504 (C.C.P.A. 1976)).

The factors that may be considered in determining whether a disclosure would require undue experimentation include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Wands, 858 F.2d at 737. "[A]ll of the [*Wands*] factors need not be reviewed when determining whether a disclosure is enabling." *Enzo Biochem, Inc. v. Calgene, Inc.* ("*Calgene*"), 188 F.3d 1362, 1371 (Fed. Cir. 1999); *see Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir.)

(noting that these factors "are illustrative, not mandatory. What is relevant depends on the facts"), *cert. denied*, 502 U.S. 856 (1991).

B. Enablement Requirement as Applied to the '850 Patent

Although determination of the issue of enablement can rest upon "factual underpinnings," *Union Pacific Resources*, 236 F.3d at 690, I find that there are no factual issues here, and that this issue may properly be determined on summary judgment.[9] As with the written-description requirement, I also conclude that the '850 patent does not comply with the enablement requirement of § 112. To practice the invention claimed in the patent, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

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[9]It is unclear whether plaintiff contends that there are any issues of material fact here. At page 6 of its memorandum of law on enablement, plaintiff itself argues that it need not demonstrate the existence of any issues of fact here because, in plaintiff's view, defendants have not adduced any evidence of nonenablement (an assertion with which I disagree, as explained below). That memorandum and plaintiff's other submissions also concentrate on trying to show why the '850 patent is enabling, rather than on showing that there are facts in dispute.

In the conclusion of its brief, however, plaintiff states that although it has "amply demonstrated that the enablement requirement is satisfied here," and though defendants "have adduced *no evidence* supporting a finding of nonenablement," plaintiff "has assumed, for purposes of this Opposition only, that Defendants will contend that there is a genuine issue regarding all the facts recited" in plaintiff's Rule 56 statement. Therefore, plaintiff states, even if the Court finds that defendants have met their initial burden under Rule 56, "the motion should be denied because there are many genuine issues of material fact."

As stated, it is difficult to tell from this whether plaintiff is asserting that there are issues of fact here or not. Even if the parties do dispute any facts, however, those facts are not material. For one thing, many of the "disputes" referenced in plaintiff's Rule 56 statement amount to little more than matters of semantics, *e.g.*, the meaning of "non-steroidal," or the parties' characterizations of, or arguments from, undisputed facts, *e.g.* whether the '850 patent "identifies" or "describes" suitable compounds. In addition, none of the facts or assertions set forth in plaintiff's Rule 56 statement would alter my conclusions of law set forth in this Decision and Order, even if I were to draw every reasonable inference relating to those facts in plaintiff's favor.

As already stated, the '850 patent essentially calls for the use of trial and error to attempt to find a compound that will selectively inhibit PGHS-2 activity in a human host, which is the method claimed by the patent. The fact that it does so does not *per se* mean that the patent fails to meet the enablement requirement. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983) (district court erred in invalidating patents for indefiniteness because of its view that some "trial and error" would be needed, since "[t]here was no evidence and the [district] court made no finding that undue experimentation was required" to practice the invention), *cert. denied*, 469 U.S. 851 (1984).

It must be remembered, however, that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech*, 108 F.3d at 1366 (quoting *Brenner v. Manson*, 383 U.S. 519, 536 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion")). Thus, while the need for some experimentation is by no means necessarily fatal, "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Id.*

Such detail is lacking here. The patent does describe how to conduct assays "for the screening of drug actions on both" PGHS-1 and PGHS-2, '850 Patent, col. 24, lines 33-34. The patent states that the claimed "invention ... provides a method to evaluate the relative inhibitory activity of a compound to selectively inhibit PGHS-2 versus PGHS-1 ...," and then goes on to describe the assay procedure. '850 Patent, col. 24, lines 60-62.

The patent also describes what to do with "[a]ny of the identified compounds" once they *have* been identified as selective PGHS-2 inhibitors. '850 Patent, col. 27, line 39. It discusses, for example, routes of administration to a host, determining an effective dose, and methods of manufacturing pharmaceutical compositions containing the compound.[10]

By its own terms, then, the '850 patent describes methods for "screening" and "evaluat[ing]" the effect of various compounds on PGHS-1 and -2 activity. It also describes some of the steps to be taken once a suitable compound has been identified, in order to make it possible to practice the claimed invention.

What the '850 patent does *not* do, however, is provide the necessary link between those two steps: actually finding a compound that works. It provides precious little guidance in the way of selecting a particular compound, or even of narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation.

Plaintiff contends that it need not have provided additional detail in this regard, because the procedures for finding the sought-after compound were well known in the art. One of plaintiff's experts, Dr. Mark J. Suto, who holds a Ph.D. in Medicinal Chemistry, states in his declaration (Docket #329) that it is his "considered opinion that, as of September 1992, persons of ordinary skill in the relevant art could have practiced the methods of claims 1-7 of the '850 patent without undue experimentation, based on the disclosure of the September 1992 application and what was well known in the art." Suto Decl. ¶ 14. Dr. Suto states that in September 1992, the use of *in vitro* assays

[10]Defendants also assert that the '850 patent fails to enable the claimed method of treating humans because it does not sufficiently disclose specific dosages, formulations, or routes of administration. Because I find the patent invalid on the grounds set forth here, I need not reach that argument.

for identifying usable compounds in medicinal research was well known and commonplace. He states that "[u]sing the disclosed *in vitro* assays [taught in the '780 application] would have permitted rapid and routine assessment of test compounds as potential selective Cox-2 inhibitors." Suto Decl. ¶ 24.

According to Dr. Suto, "the ordinary skilled person in September 1992 would have understood the ['780] application to teach that screening for selective inhibitors using the disclosed *in vitro* assays should commence with existing NSAIDs as a starting point." Suto Decl. ¶ 25.[11] He states that a medicinal chemist would have understood, from the '780 application and his knowledge of the relevant art, that one should prepare new compounds based on an initial, NSAID "lead compound." Suto Decl. ¶ 27. The Cox-2 selectivity of the new compounds, which would essentially be variants of the lead compound, would then be compared to that of the lead compound. A researcher would then determine which structural changes to the lead compound increased Cox-2 selectivity, using "routine" methods. Suto Decl. ¶ 28. The most promising compounds would then have been "assessed in several of the many *in vivo* animal models then in use for screening NSAIDs." Suto Dec. ¶ 38.

Although Dr. Suto states that a person of ordinary skill in the art would have understood much of this from reading the '780 application, nowhere does he point to any particular language in the application setting forth how to select compounds that would be likely to be of use in

[11]Dr. Suto states that as an alternative, an ordinary skilled scientist employed by a pharmaceutical corporation would have screened all compounds maintained in the corporate compound "library." Dr. Suto maintains that "[t]his approach ha[s] the potential quickly to identify novel compounds inhibiting the target of interest." Suto Decl. ¶ 30.

practicing the invention. Instead, he relies–as does plaintiff–on this hypothetical person's knowledge of the art to supply this missing information.

While it is true that a patent need not disclose that which is already well known in the art in order to be enabling, *see*, *e.g.*, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987), the Federal Circuit has cautioned:

> that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.

Genentech, 108 F.3d at 1366.

Here, far more than "minor details" are missing. Neither the patent nor the September 1992 application identify any suitable compound, nor do they explain how one can discover such a compound, except by testing compounds that "include but are not limited to nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof, as well as antisense, ribozyme, triple helix, antibody, and polypeptide molecules and small inorganic molecules." '850 Patent, col. 27, lines 29-35. As the Federal Circuit stated in *Genentech*, plaintiff cannot rectify this glaring omission simply by asserting that the necessary information would have been known to one of skill in the

art.[12] 108 F.3d at 1366; *see also Perreira v. Secretary of Dep't of H.H.S.*, 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it").

I also note that several of plaintiff's experts state that, that, based on their review of certain confidential documents obtained in discovery, as well as a statement of Peter Isakson, an employee of Searle, which was submitted in connection with an unrelated action in Great Britain (Docket #333, Ex. 12), they believe that Searle used *in vitro* assays that led to the discovery of selective

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[12]I have also considered the declarations of plaintiff's other experts: Edward A. Dennis, who holds a Ph.D. in Chemistry; Christopher J. Schofield, Ph.D., who is a lecturer in Organic Chemistry; Heather M. Wallace, who holds a Ph.D. in Biochemistry; and Eugene Segre, M.D., who has experience in clinical pharmacology and drug development.

Neither Dr. Segre's declaration (Docket #325) nor Dr. Wallace's declaration (Docket #327) addresses the issue of enablement with respect to the identification of a suitable compound. Dr. Segre's declaration is primarily concerned with whether "pharmacologists and clinicians, when *provided* by medicinal chemists with a COX-2 selective non-steroidal anti-inflammatory agent," would have been able to determine an appropriate dosage and to actually use it and evaluate its efficacy with human patients. Segre Decl. ¶ 7 (emphasis added). Dr. Wallace's declaration mostly provides background information relating to NSAIDs in general.

Drs. Dennis and Schofield both opine that the '780 application would have enabled one of ordinary skill in the art to practice the inventions claimed in the '850 patent without undue experimentation as of September 1992. Dennis Decl. (Docket #326) ¶ 34; Schofield Decl. (Docket #334) ¶¶ 10, 29. The rest of their declarations, however, fail to support that conclusion. Dr. Dennis's declaration, for example, focuses largely on how a person of ordinary skill in the art would understand the use and function of the screening assay, rather than on actually discovering a suitable compound. Likewise, Dr. Schofield offers virtually no explanation of why he believes that the '780 application would have enabled a skilled team of scientists in September 1992 to practice the claimed invention without undue experimentation; his assertion to that effect is wholly conclusory.

I therefore find that these declarations fail to support plaintiff's assertion that the '850 patent meets the enablement requirement. *See Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 876 (Fed. Cir. 1998) (patentee failed, through the statements of its experts, to raise a genuine issue of material fact precluding summary judgment, since "the expert declarations [we]re wholly conclusory, devoid of facts upon which the affiant[s'] conclusions, as experts, were reached"); *Gleason Works v. Oerlikon Geartec, AG*, 141 F.Supp.2d 334, 341 (W.D.N.Y. 2001) ("a party cannot defeat a well-founded motion for summary judgment simply by submitting an expert's 'naked opinions'") (quoting *Weigel v. Target Stores*, 122 F.3d 461, 469 (7th Cir. 1997)).

PGHS-2 inhibitors. According to Dr. Suto, Searle's effort to identify such compounds began in August 1992. By May 1993, Searle had screened more than 600 compounds in *in vitro* assays, and had identified a number of selective PGHS-2 inhibitors.

The point, apparently, is to show that researchers at Searle, using the methods taught, and information contained, in the '780 application, were able to identify selective PGHS-2 inhibitors.[13] The fact that it took Searle about eight months to identify some PGHS-2 selective inhibitors, after screening over 600 compounds, however, does not show that the '780 application was enabling in the absence of undue experimentation. While I recognize that the test for undue experimentation is not "merely quantitative," *PPG Indus.*, 75 F.3d at 1564, this nevertheless demonstrates that considerable work and research was needed in order to turn the invention claimed by the '850 patent into reality, and the patent supplies very little guidance with respect to the direction in which the experimentation should proceed. *See National Recovery Technologies*, 166 F.3d at 1198 ("The most that [the patentee] can be credited with is promising the ideal result in [the patent claims], even though the specification does not completely deliver on this promise").

In short, although the '850 patent describes an assay for determining whether a given compound possesses certain desired characteristics, and identifies some broad categories of compounds that *might* work, these descriptions, without more precise guidelines, amount to little more than "a starting point, a direction for further research." *Genentech*, 108 F.3d at 1366. *See also Calgene*, 188 F.3d at 1374 ("the teachings set forth in the specifications provide no more than a

[13]Plaintiff does not explain why, if Searle relied on information set forth in the '780 application, Searle began looking for a PGHS-2 inhibitor in August 1992, a month before the '780 application was filed.

'plan' or 'invitation' for those of skill in the art to experiment practicing [the claimed invention]; they do not provide sufficient guidance or specificity as to how to execute that plan"); *National Recovery Technologies*, 166 F.3d at 1198 (stating that patent-in-suit "recognizes a specific need ... and suggests a theoretical answer to that need. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement"). The '850 patent does not describe the claimed invention in terms that will "enable any person skilled in the art ... to make and use" the invention. At most, its description will enable a person of ordinary skill in the art to *attempt to discover* how to practice the claimed invention. That is not enough.

CONCLUSION

Defendants' motion for summary judgment of patent invalidity for failure to meet the written-description requirement of 35 U.S.C. § 112, ¶ 1 (Docket #170), and defendants' motion for summary judgment of patent invalidity for non-enablement (Docket #255) are granted, and the complaint is dismissed.

Plaintiff's cross-motion for summary judgment that the '850 patent is not invalid for failure to meet the written-description requirement (Docket #207) is denied.

IT IS SO ORDERED.

DAVID G. LARIMER
United States District Judge

Dated: Rochester, New York
March 5, 2003.